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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,059	10/06/2003	Domonkos Horvath	HORVATH1	4090

1444 7590 10/18/2005

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EXAMINER	
BEISNER, WILLIAM H	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

✓

Office Action Summary	**Application No.** 10/678,059	**Applicant(s)** HORVATH, DOMONKOS
	Examiner William H. Beisner	**Art Unit** 1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2005 and 28 July 2005*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-34* is/are pending in the application.
  4a) Of the above claim(s) *9-29 and 34* is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *30-33* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
  Paper No(s)/Mail Date *7/28/05*.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 25-29 and 34 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The newly filed claims are grouped as follows:

Group I, claims 25-28, 31/25, 32/25, 33/25 and 34

Group II, claims 29, 31/29, 32/29 and 33/29

Group III, claims 30, 31/30, 32/30 and 33/30.

The inventions as presently claimed in Groups I to IV are deemed to be independent inventions.

The carrier feature required of the invention of Group I is not required of the inventions of Groups II or III. The microstructural indentations feature required of the invention of Group II is not required of the invention of Groups I or III. The attached osteoblasts feature required of the invention of Group III is not required of the inventions of Groups I or II.

Since applicant has received an action on the merits for the originally presented invention, which includes the features associated with the invention of Group III, claims 30, 31/30, 32/30 and 33/30, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25-29 and 34 along with previous claims 9-24 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. This application contains claims 9-24 drawn to an invention nonelected with traverse in the reply filed 1/19/2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

3. The information disclosure statement filed 7/28/05 has been considered and made of record.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 30, 31/30, 32/30 and 33/30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horvath et al.(WO 01/91663) in view of Dee et al.(WO 97/25999) or Meyer et al.(US 6,280,760).

The reference of Horvath et al. discloses a device for regeneration of tissue that includes a membrane (4) that is permeable for the exchange of nutrients and is structurally stable. The membrane has a surface that is to be bonded to a tissue (2) to be regenerated (See Figure 1). The device includes means or device (5,6) for moving membrane (4) with a certain pulling force and speed.

With respect to claim 30, the reference is silent as the use of a means for biological anchoring and adhesion for tissue or bone cells on the side of the membrane facing the tissue to be regenerated.

The references of Dee et al. and Meyer et al. both disclose that it is known in the art to provide the surfaces of implant devices with peptides for altering the cell adhesion properties of the implant material (See the abstracts of both references).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the membrane of the primary reference of Horvath et al. with peptides as suggested by the references of Dee et al. or Meyer et al. for the known and expected result of enhancing the adhesion of osteoblasts to the surface of the membrane which is required for the tissue regeneration process.

Also with respect to claim 30, osteoblasts would be anchored to the surface of the membrane since bone is being regenerated and the references of Dee et al. and Meyer et al. disclose that the peptide coating is for the adhesion of osteoblasts.

With respect to claim 31/30, the tissue cells are bone cells.

With respect to claims 32/30 and 33/30, the peptides suggested by the references of Dee et al. and Meyer et al. meet the claim limitations “protein molecules” or “short-chain molecules”.

6. Claims 30, 31/30, 32/30 and 33/30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horvath et al.(WO 01/91663) in view of Robinson (US 5,839,899) and either Dee et al.(WO 97/25999) or Meyer et al.(US 6,280,760).

The reference of Horvath et al. discloses a device for regeneration of tissue that includes a membrane (4) that is permeable for the exchange of nutrients and is structurally stable. The membrane has a surface that is to be bonded to a tissue (2) to be regenerated (See Figure 1). The device includes means or device (5,6) for moving membrane (4) with a certain pulling force and speed.

If it is determined that the membrane (4) of the reference of Horvath et al. is not "permeable for the exchange of nutrients at least for serum and structurally stable", the reference of Robinson discloses that it is known in the art to employ permeable membranes for guided-tissue regeneration so as to promote the exchange of nutrients and blood supply between the graft and the overlying tissue (See column 4, lines 40-67).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a porous membrane for the known and expected result of providing nutrient exchange as is suggested by the reference of Robinson.

With respect to claim 30, the reference is silent as the use of a means for biological anchoring and adhesion for tissue or bone cells on the side of the membrane facing the tissue to be regenerated.

The references of Dee et al. and Meyer et al. both disclose that it is known in the art to provide the surfaces of implant devices with peptides for altering the cell adhesion properties of the implant material (See the abstracts of both references).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the membrane of the primary reference of Horvath et al. with peptides as suggested by the references of Dee et al. or Meyer et al. for the known and expected result of enhancing the adhesion of osteoblasts to the surface of the membrane which is required for the tissue regeneration process.

Also with respect to claim 30, osteoblasts would be anchored to the surface of the membrane since bone is being regenerated and the references of Dee et al. and Meyer et al. disclose that the peptide coating is for the adhesion of osteoblasts.

With respect to claim 31/30, the tissue cells are bone cells.

With respect to claims 32/30 and 33/30, the peptides suggested by the references of Dee et al. and Meyer et al. meet the claim limitations “protein molecules” or “short-chain molecules”.

7. Claims 30, 31/30, 32/30 and 33/30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gogolewski et al.(US 5,676,699) in view of Dee et al.(WO 97/25999) or Meyer et al.(US 6,280,760).

The reference of Gogolewski et al. discloses a device for regeneration of tissue that includes a membrane (1) that is permeable for the exchange of nutrients and is structurally stable. The membrane has a surface that is to be bonded to a tissue (inner surface of the cylindrical membrane) to be regenerated (See Figures 2-4). The device includes means or device (9) that is capable of moving the membrane (1) with a certain pulling force and speed.

With respect to claim 30, the reference is silent as the use of a means for biological anchoring and adhesion for tissue or bone cells on the side of the membrane facing the tissue to be regenerated.

The references of Dee et al. and Meyer et al. both disclose that it is known in the art to provide the surfaces of implant devices with peptides for altering the cell adhesion properties of the implant material (See the abstracts of both references).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the membrane of the primary reference of Horvath et al. with peptides as suggested by the references of Dee et al. or Meyer et al. for the known and expected result of enhancing the adhesion of osteoblasts to the surface of the membrane which is required for the tissue regeneration process.

Also with respect to claim 30, osteoblasts would be anchored to the surface of the membrane since bone is being regenerated and the references of Dee et al. and Meyer et al. disclose that the peptide coating is for the adhesion of osteoblasts.

With respect to claim 31/30, the tissue cells are bone cells.

With respect to claims 32/30 and 33/30, the peptides suggested by the references of Dee et al. and Meyer et al. meet the claim limitations "protein molecules" or "short-chain molecules".

Response to Arguments

8. With respect to the potential rejection of claim 30 under the same grounds as previously applied against claims 2 and 5, Applicant argues (See pages 14 and 15 of the response filed 7/22/05) that the cited prior art does not disclose a membrane comprising a surface consisting of osteoblasts. Applicant also states that the manufacture of membranes and the culturing of living cells are greatly different technologies, which makes it unlikely that the skilled person would

combine information from these two fields to construct a membrane comprising a surface of osteoblasts.

In response, the Examiner is of the position even if the membrane of the modified primary reference does not include osteoblasts prior to use, during use of the device as required by the modified primary reference, osteoblasts will be attached to the membrane by the means for biologically anchoring and meets the structure required of the language of independent claim 30.

In response to applicant's comments concerning the combination of non-analogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, all of the references of Horvath et al., Dee et al., Meyer et al., Robinson and Gogolewski et al. are all within the same field of endeavor, implant-type devices that require the adhesion of osteoblasts to the surface of the implant device during use.

Note Applicants' arguments with respect to independent claims 25 and 29 and dependent claims thereof have not been responded to since these claims have been withdrawn for the reasons set forth previous.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner
Primary Examiner
Art Unit 1744

WHB